REPORT ON A TRAINING WORKSHOP ON VOLUNTARY COUNSELLING AND TESTING (VCT) FOR LEISHMANIA/HIV

WHO/UNAIDS

25-29 April 1999 Held at the Ararat Hotel, Addis Ababa Ethiopia

Report Prepared by John Green, Temporary Adviser

1. Background

Leishmaniasis is a protozoan disease spread by the bite of the sandfly. Transmission can be anthroponotic or zoonotic with different animal reservoirs in different parts of the world. There are twenty or more species of *leishmania* and the symptoms of the disease vary with the infecting species and with host factors. The disease is present in cutaneous, diffuse cutaneous, mucocutaneous and visceral forms, the latter usually being fatal if untreated. Leishmaniasis is present in the Mediterranean area of Europe and North Africa, in Southern and Central America, in Africa - particularly the Horn of Africa - and in the Indian sub-continent and parts of South East Asia.

Co-infection with leishmaniasis and HIV is becoming more common as HIV spreads in *leishmania*-endemic areas. Co-infection in the Indian subcontinent and in sub-Saharan Africa where rates of HIV and *leishmania* infection are high are a matter of particular concern, however co-infection is a major problem in all areas where the two diseases co-exist. Co-infection creates particular difficulties in diagnosis and treatment of leishmaniasis and the prognosis of those who are co-infected are poor. Even where HIV viral load falls and CD4+ counts rise in patients treated with HAART, the treatment of leishmaniasis in the co-infected patient remains problematic and the long-term prognosis is poor. Because co-infected individuals have high relatively levels of the *leishmania* parasite in their blood the potential for anthroponotic transmission via sandflies is increased. Cases of anthroponotic transmission amongst injecting drug users in Europe have also been reported. Thus co-infection is likely to adversely affect the epidemiology of leishmaniasis and increase the potential for epidemic spread.

The workshop was intended to address two issues:

- To develop guidelines for the practical diagnosis and management of cases of *leishmania*/HIV co-infection.

- To provide training in VCT for HIV for clinicians working with leishmaniasis patients.

2. Participants

A list of participants in the workshop is given at Annex 2. The workshop had an excellent geographical spread of participants and all participants were concerned actively in either treatment of HIV/leishmaniasis, in disease control or in the management of health care delivery systems.

3. Facilities/Logistics

These were excellent.

4. Overall design of workshop

The VCT element of the workshop was built loosely around the WHO manual ***Training of Trainers in STD Counselling, WHO Regional Office for the Western Pacific: Manila 1998.*** This provides clear and practical exercises and materials for VCT training. Importantly, it also provides necessary flexibility, which allows modifications of the programme to meet different circumstances. Several modifications were made to the suggested programme of the workshop set out in the manual:

- In most cases of suspected co-infection VCT is likely to be health-worker initiated. In other words the health care worker is likely to be faced with the issue of raising the question of HIV and of HIV testing with the patient on the basis of the symptoms with which they present and/or their response to treatment of leishmaniasis. The patient may have no inkling that infection is a possibility. One section of the workshop was, therefore, concerned with exercises and presentations around raising the issue with the patient. While this issue comes up in other contexts, including within an STD counselling framework, it is particularly important and difficult in co-infections where the infection other than HIV is not sexually transmitted. The context for raising HIV is not present in the way that it is in an STD context and, therefore, the clinician is faced with raising the issue 'from cold'.

- Health care workers involved with leishmaniasis have varying levels of familiarity with STD's other than HIV. Even amongst the workshop participants, a particularly well-informed group of workers, knowledge and experience varied considerably. Intercurrent STD's, particularly genital ulcer disease, promote transmission of HIV to sexual partners as well as causing considerable morbidity in their own right and, in some cases, possibly promoting HIV disease progression. Programmes aimed at controlling HIV including those aimed at co-infection are likely to have increased effectiveness where control of other STD's is included, although HIV epidemic stage and the type of prevalent STD's may influence the relative importance of the STD control element. It would seem optimal for newly identified HIV+ individuals with co-infection and their sexual partners should be offered routine screening for other STD's where diagnostic facilities are available. Elsewhere patients and contacts can be syndromically managed. While there was coverage of this issue at a theoretical level and discussion of how such management might be integrated in practice in different places the workshop did not formally cover syndromic management. This should probably be a larger part of future training for health workers in co-infection.

- In order to achieve the other objective of the workshop, the development of guidelines for management/diagnosis of co-infection, elements of the manual had to be shortened. In order to save time while maintaining content the sections on non-verbal elements of counselling, common counselling errors and basic

counselling skills were provided as presentations rather than as exercises. This was acceptable with participants with existing high skills in dealing with patients and a keen awareness of social and psychological factors in patient management but would probably be less acceptable with participants without these characteristics.

- The Manila role-plays were area-specific and had to be modified. It was necessary to adapt role-plays in ways which reflected a wide range of cultural backgrounds of participants. Additionally, most VCT in co-infection is provoked by patient leishmaniasis symptoms and is likely to be clinician-initiated rather than the patient initiating VCT. However the basic framework of the Manila role-plays was good and adapting them to a broader and different cultural background was straightforward.

- The workshop contained an increased element of input on sexual behaviour and models of sexual behaviour. Where health care workers are not directly involved in sexual health provision of more information and opportunity for discussion on sexual issues generally is required.

- The many and varied cultural backgrounds of the participants allowed discussion on commonalities and differences in sexual behaviour within and between countries. This allows common themes in human sexual behaviour to be more easily drawn out.

With these modifications the Manila course manual proved helpful and worked well in a different context from the one it was devised for.

5. Programme

Because of the importance attached to developing guidelines for the diagnosis and management of leishmaniasis the programme originally devised for the workshop was deviated from at several points. The original programme is given at Annex 1.

As part of the programme information was gathered on the current position with respect to co-infection in the countries represented. A summary of the situation is provided at Annex 4.

6. Recommendations

Several important issues came out of the workshop which are of some importance:

- Co-infection is an important consideration in the treatment and prognosis of both leishmaniasis and HIV disease. The pattern of disease seen in leishmaniasis can be an important indicator of probable HIV infection. The

presence of large numbers of immunocompromised individuals in leishmaniasis endemic regions may have important implications for the spread of leishmaniasis, particularly through anthroponotic transmission. The introduction of VCT programmes in leishmaniasis centres and services is timely and important to the control and treatment of both diseases.

- It is important that local leishmaniasis programmes should co-operate closely with, and be involved in, local country programmes for AIDS, including training programmes in VCT and HIV/STD treatment and control.

- The maintenance of close links between UNAIDS and the WHO leishmaniasis programme is likely to prove increasingly important as the incidence of co-infection rises.

- As UNAIDS policy identifies, control of other sexually transmitted infections is an important part of the control of HIV. Many individuals with HIV infection will have intercurrent sexually transmitted diseases which will need to be identified and treated appropriately. In developed countries routine screening of individuals with HIV infection for other sexually transmitted infections, at the time of diagnosis, combined with advice on the avoidance of new infections is important. In countries where diagnostic facilities are absent or poor a syndromic approach to control and treatment of sexually transmitted infections is the optimal strategy. WHO provides excellent materials on syndromic management of sexually transmitted infections and has an excellent series of workbooks which might, with considerable advantage, be distributed to leishmaniasis centres. Training programmes on co-infection should provide an element concerned with syndromic management.

- Co-infection provides a number of specific difficulties for the clinician. In particular testing may be suggested by the health care worker on the basis of the symptoms or treament response of the patient. In many cases the health care worker may be more or less certain that the patient will be infected on the basis of the other symptoms the patient presents. This is a different starting point from those situations where VCT is initiated by the patient or is being suggested to the patient as part of a general approach to particular categories of patient, as for instance in antenatal testing. Training programmes addressing VCT in co-infection need to address this problem directly, particularly the issue of how the health care worker can optimally raise and discuss the issue with the patient.

- As in all VCT programmes, confidentiality is an important consideration. If patients are to feel confident that they can be tested and social problems for them in the community are to be avoided they need to feel that their confidentiality will be protected as far as possible. Patients are often terrified that their status will become known and that they will be rejected, particularly

in relatively small communities. HIV infection is clearly a much more stigmatised disease than leishmaniasis and leishmaniasis centres introducing VCT will need to pay particular attention to examining the issue and taking practical steps to ensure that information is kept as confidential as possible and that they are in a position to allay patient fears. Simple steps can be very helpful such as moving from sending named samples for testing to the use of patient-identifier numbers or the health care professional drawing blood rather than sending the patient to the laboratory. Relatively minor local changes can often improve confidentiality with no cost and little effort once the problem is identified.

- It is important that the guidelines on diagnosis and management of co-infection should be as widely disseminated as possible since they provide important practical help to health care workers in the area on practical management of the condition. The guidelines are attached at Annex 3.

ANNEX 1: AGENDA

WORLD HEALTH ORGANIZATION
Organisation mondiale de la Santé

UNAIDS
UNICEF • UNDP • UNFPA • UNDCP
UNESCO • WHO • WORLD BANK

Training workshop on Voluntary Counselling and Testing (VCT) for *leishmania*/HIV
Ararat Hotel, Addis Ababa, Ethiopia
25-29 April 1999

AGENDA

25 April 1999

08:45 - 09:30	**Opening Session** **Dr H. Negassa,** MOH, Addis Ababa **Dr Babanyi**, Acting WR, Addis Ababa **Dr K. M'Nyamuryekung'e**, UNAIDS Representative, Addis Ababa **Dr P. Desjeux**, CSR/EDC, WHO/HQ
09:30 - 10:00	**Session 1:** Introductions, plan and processes of workshop, review of objectives
10:00 – 10:30	**Session 2: (Part 1)** Co-infection leishmaniasis and HIV infection background
10:30 - 11:00	******** ***BREAK*** ********
11:00 - 13:00	**Session 2: (Part 2)** Co-infection leishmaniasis and HIV infection background
14:00 - 15:30	**Session 3:** Sexual health: counselling and communication Listening and non-listening Communicating non-verbally

15:30 - 16:00

******** ***BREAK*** ****

16:00 - 17:00

Session 4:
Principles and process of counselling

26 April 1999

09:00 - 10:30

Session 5:
Sex and sexuality, sexual terminology and varying sexual practices worldwide

10:30 - 11:00

******** ***BREAK*** ****

11:00 - 13:00

Session 6:
Safer sex, condom use and negotiating safer sex

14:00 - 15:30

Session 7:
Taking a sexual history

15:30 - 16:00 ******** ***BREAK*** ****

16:00 - 17:00 **Session 8:**
Identifying levels of risk

27 April 1999

09:00 - 10:00

Session 9:
HIV pre-test counselling

- Roleplaying and case-studies

10:30 - 11:00

******** ***BREAK*** ****

11:00 - 13:00

Session 10:
Obtaining informed consent

14:00 - 15:30

Session 11:
Prevention counselling

15:30 - 16:00

********* ***BREAK*** *********

16:00 - 17:00

Session 12:
Principles and process of counselling

28 April 1999

09:00 - 10:30

Session 13:
Giving the news of a positive result

- roleplaying and case-studies

********* ***BREAK*** *********

10:30 - 11:00

	Session 14:
11:00 - 13:00	Giving news of a positive result - breaking the bad news and managing the result-giving
14:00 - 15:30	**Session 15:** Informing partners
15:30 - 16:00	***** *BREAK* *****
16:00 - 17:00	**Session 16:** Planning for future crisis management

29 April 1999

09:00 - 10:30	**Session 17:** Writing local plans
10:30 - 11:00	**Session 18:** Integrating HIV work into the local services
11:00 - 13:00	***** *BREAK* *****
14:00 - 15:30	**Session 19** Evaluation
15:30 – 16:00	**Formal Closing**

Dr John Green
Moderator

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ANNEX 2: WORKSHOP PARTICIPANTS

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ANNEX 3: VL / HIV CO-INFECTION GUIDELINES

(1) EPIDEMIOLOGY

- There is a pressing need to know more precisely the extent of VL/HIV co-infection in the world, particularly in some selected areas such as East Africa and the Indian subcontinent, and to evaluate the trends.

- HIV infection increases the rate of VL cases: 100% of immunosuppressed people, infected by *Leishmania* will develop clinical VL; in contrast only 1 in every 8-10 infected persons will develop VL if not immunosuppressed.

- VL/HIV co-infected patients act as a reservoir (anthroponotic cycle) and become a potential source of infection for the sandfly vector.

(2) CLINICAL PRESENTATION OF VL IN THE CO-INFECTED INDIVIDUALS

- VL can be an opportunistic infection (sometimes the first one) in HIV+ patients.

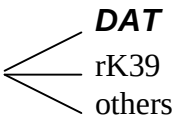
- VL is more frequent in adults with HIV than in HIV non-infected individuals possibly as a result of reactivation of childhood infection.

- Typical clinical presentation of VL can be masked by another concomitant opportunistic disease.

- VL atypical cases are more frequent in co-infected individuals.

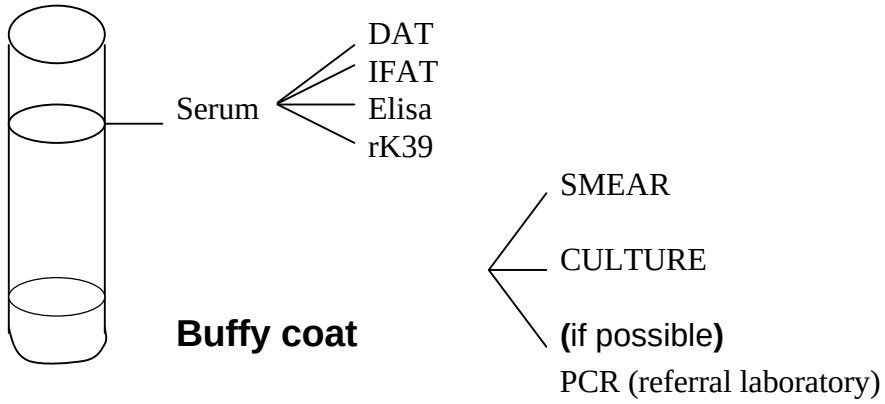
- Diffuse cutaneous leishmaniasis or visceralization of cutaneous leishmaniasis are much more likely in co-infected individuals.

(3) DIAGNOSIS OF VL: Methods

(a) Finger prickling 

(b) Whole Blood (anticoagulated) (EDTA treatment)

+ sedimentation
+centrifugation
+leucocyto - centrifugation



(c) Puncture/aspirate of spleen, bone marrow, lymph node:

- smear
- and culture (if possible)

(4) Provide specific recommendations for each test/technique
(see document WHO/LEISH 96.39)

Serology	SMEAR	
+	-	a) treatment depending level of antibodies b) 2nd step
-	+	Treatment
+	+	Treatment
-	-	to perform 2nd step if still suspected

(4) **DIAGNOSIS OF VL and HIV** : **Indications**

- ***When to request an HIV serology in a proven VL case?***
  - Ideally the aim should be the systematic detection of HIV infection amongst adult VL cases, but always within the national policy framework..
  - In case of HIV stigma or other opportunistic infections

- Where VL occurs in an individual from a well-defined high HIV-risk population (truck drivers, sex workers, injecting drug users, patients suffering from other STDs) or in migrants from areas where HIV prevalence is high.

- In individuals with characteristics known to be associated with high risk of HIV infection in the local area (based on reports of co-infected cases in each area).

- In individuals whose VL shows unusual characteristics or where the response to treatment is not as expected. In particular:

    - atypical cases (as compared to other cases observed in the same area)
    - Non-responding or relapsing cases after treatment based on WHO recommended regimen
    - Unexplained severe toxicity from treatment
    - Parasitologically proven cases which are serologically negative.
    - Where another severe intercurrent infection occurs with the VL.

- In areas of where HIV/AIDS and leishmaniasis are known to show considerable overlap (as in Southern Europe) the HIV test should be offered in every adult VL case and in atypical cutaneous cases.

- Unexpected increases in mortality rate associated with VL in a particular geographical area should raise the possibility that co-infection may be behind the shift

- ***When to look for VL in a previously known HIV+ patient?***

    - in case of unexplained or persisting fever, pancytopenia, pallor, bleeding, visceromegaly (excluding or treating other mimicking diseases e.g. malaria, tuberculosis, typhoid, brucellosis)

    - in cases where symptoms such as diarrhoea, or abnormal laboratory tests (e.g. thrombopenia), remain unexplained after a complete workup.

(5) TREATMENT

- HIV treatment when/where possible (antiretroviral therapy)
- VL treatment:

- Pentavalent antimonials ($Sb^{+5)}$: 20 mg Sb^{+5}/Kg/day/ IM or IV during 28 days;
- Amphotericin B in areas of Sb^{+5} resistance or unresponsive or relapsing cases:

1 mg/kg/every other day by /IV/for 15-20 doses.

- Others? Miltefosine (25mg/12h/28 days)

Be aware that in co-infected individuals there is:

- High mortality rate
- Increased risk of toxicity
- Poorer treatment outcome
- Increased relapsing

(6) **PREVENTION/CONTROL**

It is important that :

- Action on VL should be integrated into STD/HIV national programme where possible
- Action on VL should be integrated into malaria national programmes where possible
- Progressive use of insecticide impregnated bednets is recommended starting with high risk groups and extending to global coverage.
- Special attention is recommended in areas where transmission of VL is anthroponotic.
- Particular steps are needed at the case level to control co-infection and restrict VL transmission. The action needed varies with the status of the individual case:

(a) HIV(-)/ VL(+) or suspected co-infection

- Use of bednets (in anthroponotic cycles) as co-infected patients are source of infection for the vectors.
- Close follow up (frequent relapses likely)

(b) HIV (+) VL(-)

- Particular attention to avoidance of transmission of HIV to others
- Use of bednets for those who migrate to highly VL endemic areas from non-endemic areas (non-immune)

(c) HIV (-) VL(+)

- Reinforcement of prevention methods to avoid HIV acquisition
- Use of bednets in areas of anthroponotic transmission.

(d) HIV(-) VL(-)

- Follow up (periodic screening) if in VL endemic area and preventive actions for HIV.

(7) VOLUNTARY COUNSELLING AND TESTING (VCT) IN THE CONTEXT OF HIV / VL CO-INFECTION

- HIV testing should always be with the informed consent of the individual

- Where testing is being offered on the basis of particular symptoms, a treatment response profile, a pattern of relapse or laboratory test results which the clinician believes are likely to be the result of co-infection, this should be explained to the individual

- VL services will need to consider carefully the provision they make for confidentiality – because of the stigma attached to HIV – if patients are not to be deterred from being tested and are not to be exposed to the risk of adverse social consequences

- Where HIV VCT is being offered to co-infected patients provision needs to be made to provide VCT to their partners and contacts and to their children

- Because of the close linkages between HIV and other STD's it is important to provide counselling, diagnostics and treatment for other STD's to individuals for whom HIV VCT is being offered. Where appropriate diagnostics are not available, a syndromic approach should be adopted

ANNEX 4: CO-INFECTION BY COUNTRY

ETHIOPIA

Leishmaniases in Ethiopia are mainly due to *L.donovani s.l* and *L.aethiopica,* causing visceral (VL) and cutaneous leishmaniasis (CL), respectively. CL due to *L.aethiopica* is a zoonosis, with the rock hyraxes as reservoirs and *P.pedifer* and *P.longipes* as vectors, restricted to the cool central highlands. VL in Ethiopia is mostly considered anthroponotic occurring in two district ecologies, with *P.martini* and *P.celiae* as vectors associated with the eroded termite hill ecology in the South, and *P.orientalis* associated with *Acccia-Balanites* vegetation in southwest and northwestern parts of the country.

In most endemic areas, community prevalences of leishmania infection, as gauged by leishmanin skin test, range from 20% to 80%. Similarly, incidence rates of overt VL range from 5/1000 to as high as 13/1000 in some selected communities. The Ochollo CL endemic foci in the South, Konso VL endemic area in southwest, and the Metema-Humera plains in northwest are the most important endemic sites in the country. The Metema-Humera lowlands are notable for the occurrence of outbreaks of the disease in the 1960s, 1970s and quite recently since 1995/6 following large scale agricultural development projects which had attracted an influx of huge labour force from the surrounding highlands. This region adjoins the vast VL endemic areas of the Sudan in the west.

HIV in Ethiopia is continuing to spread at alarming rate. Using conservative estimates, the overall prevalence in adults is around 5%. This figure could be as high as 50% in some risk groups like the commercial sex workers. With ruralization of HIV infection on one hand and large scale human settlement and agricultural development on the other, the condition for the overlap of leishmania-HIV co-infection are increasingly optimized with drastic effect in the epidemiology of both diseases. So far in Ethiopia, 72 cases of co-infection have been officially reported and the actual estimated are well over 250 cases. A community based HIV sero-prevalence study carried in the main leishmania endemic areas in the country. In Ochollo, about one-fifth of the population shows evidence of past or present CL. The HIV rate in individuals with active CL was 21%, compared to only 2% in subjects without CL. In this cross-sectional study, the clinical presentations of CL in HIV co-infected patients were no different from the usual features seen in HIV-negative patients. In the Aba-Roba VL focus in Konso, 5.4/1000 of the population have VL, and community sero-prevalence of HIV infection was estimated to be less than 1% while the rate among VL was 3.8%. In the Metema-Humera focus in North West, where the population largely consists of settled migrants, across the border from Gedaref and seasonal workers, the HIV rate risen from 5% in 1995 to 11% in 1997. The HIV rate among commercial sex workers was as high as 52%. During a survey, 1.7% of HIV + appeared serologically positive for leismaniasis (DAT+). Among DAT+ people, 7.1% were positive for HIV. The HIV rate in cases of active and past VL was estimated to be 38%.

Within Ethiopia, as in other countries in sub-Saharan Africa, rates of HIV infection amongst sex workers are high. This is particularly the case in urban areas such as Addis Ababa. Condoms are readily and cheaply available. However the rate of usage of condoms is low amongst Ethiopians generally and sex workers find it difficult to get customers to use condoms. Since competition between sex workers for customers is considerable they are in a weak position to insist. Use of paid sex, particularly by urban males, is widespread. Men typically marry in their early to mid-twenties and pre-marital sex for women is not generally socially acceptable although it does occur. Migration to the cities of young men in search of work is considerable. Social constraints on sexual behaviour are reduced under such circumstances since individuals are away from their own communities.

In the capital city, Addis Ababa, where leishmaniasis is not endemic, the number of cases of VL from known endemic areas are increasing, and 60% are HIV positive. Cases are also coming from a previously unknown focus in the Awash valley, where up to 80% of the population are leishmanin positive. Co-infected patients conform to the usual pattern, near are 28 years, male: female 27:1, initial antimony "response" of about 60%. However, most patients relapse in 6 months with an estimated in hospital death as high as 61% partly due to nosocomial bacterial infections.

Various serological tests have been evaluated in HIV-VL suspects in Ethiopia. The performance of Direct Agglutination Test was quite satisfactory with a sensitivity and specificity of well over 95%..Similarly, *r*K39- dipstick (corixa) had a sensitivity of 85% and specificity of over 95%.

The leishmaniasis control programme in Ethiopia is relatively well-established. Individuals involved in leishmaniasis control are often, however, unfamiliar with STD's and HIV treatment and control. It is important that they should receive appropriate input and support in these areas.

INDIA AND NEPAL

Leishmaniasis is highly endemic in parts of India and Nepal. Rates of HIV infection in the Indian subcontinent generally are high. However at present the areas which have high levels of leishmaniasis, particularly in the Gangetic belt, do not have high levels of HIV infection. It is more or less inevitable that this situation will change in the future as HIV spread continues in the Indian subcontinent. While co-infection is uncommon at the moment it is likely to become more common.

Since much of the transmission of *leishmania* in India is believed to be anthroponotic the arrival of co-infection could have a major impact on the dynamics of leishmaniasis. Co-infected individuals are known to infect a considerably greater number of sandflies than individuals with leishmaniasis only. Therefore there is a risk that the arrival of co-infection may provoke more and more severe epidemics of leishmaniasis.

In both India and Nepal there is population movement from rural areas to urban areas and there are problems associated with migrant workers moving within countries and, in some cases, across borders. There are also substantial numbers of sex workers in both countries. This pattern, which is not dissimilar from that seen in sub-Saharan Africa and in parts of South East Asia is probably related to the rapid spread of HIV in parts of the sub-continent.

Monitoring of leishmaniasis/HIV co-infection is particularly important in the sub-continent at this time. It is also important to get good information on levels of HIV infection in VL endemic areas and to ensure that the HIV control programmes in these areas are as effective as possible. As with other opportunistic infections associated with HIV-related immunocompromise such as tuberculosis there is a major danger that co-infection may lead to the wider spread of VL in the HIV negative population.

ITALY FRANCE AND SPAIN

Most visceral leishmaniasis in Italy, France and Spain was in children. The main reservoir is the dog. With the arrival of HIV, however, injecting drug users have become at particular risk of leishmaniasis in adulthood. Atypical manifestations are common and the disease is particularly difficult to treat in the immunocompromised individual with frequent relapses, reduced treatment effectiveness and severe disease. Even where effective HAART results in an improvement in immune functioning and a low viral load the impact on the course of the disease in the patient with established leishmaniasis is often minimal. In at least two cases leishmaniasis has been associated with an atypical *leishmania*.

Spread of the disease is mainly zoonotic in Southern Europe. However anthroponotic spread through the sharing of injecting equipment occurs in injecting drug users. Given the number and wide distribution of *leishmania* parasites in many co-infected individuals

there is some concern about the potential for some sandfly-mediated anthroponotic transmission occurring.

Particularly in Italy, but also in other Southern European countries, there are numbers of sex workers from areas of high type 2 (mainly heterosexual) spread of HIV. Such individuals may come from areas where leismaniasis is rare or unknown and therefore be at risk of acquiring the disease and becoming co-infected.

Because leishmaniasis tends to be dealt within an infectious disease context rather than in a genitourinary medicine context screening for intercurrent STD's is not always routine. The availability of excellent laboratory facilities mean that such screening could be readily applied.